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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,625	03/09/2001	Elizabeth A. Wang	5160C-CON	2656

7590

11/19/2004

FINNEGAN, HENDERSON, FARABOW  
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1300 I STREET, N.W.  
WASHINGTON, DC 20005-3315

EXAMINER
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ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/804,625

Applicant(s)

WANG ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-26, 29, 30, 33, 35, 36, 38, 39, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 30 is/are allowed.
- 6) ☒ Claim(s) 24, 25, 29, 33, 35, 36, 38, 39 and 42 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☒ Claim(s) 41 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The amendment filed 09/09/2004 has been entered. Claims 24-26, 29, 30, 33, 35, 36, 38, 39, 41, 42 are pending. Claim 41 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that it is drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

#### **Maintained Formal Matters, Objections, and/or Rejections:**

##### ***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Applicants' amendment to the specification has been considered. However, the reference to U. S. Application Nos. 943,532 and 880,776 does not include the relationship (i.e., continuation, divisional, or continuation-in-part) between the 943,532 and 880,776 applications and/or between the 943,532 and 880,776 applications and any other application. Note that, according to 1268 OG 89 (18 March 2003), the following statement is improper: "This application is a continuing application of Application Nos. C, B, and A." On the other hand, the

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following statement is proper and acceptable: "This application is a continuation of Application No. C, filed - , which is a continuation of Application No. B, filed - , which is a continuation of Application No. A, filed - ." Note also that the reference to U. S. Application No. 07/028,280 appears to be an error. Applicants may have intended to refer to U. S. Application No.

07/028,285.

***Claim Rejections - 35 USC § 112***

Claims 33, 36, 39, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim(s) 33, 36, 39, 42 are indefinite over the recitation of "stringent conditions."

Applicants argue that stringent hybridization conditions are defined in the specification at page 23, lines 25-27 and in the enclosed copy of Maniatis. Applicants also submit copies of six U. S. Patents containing claims reciting "stringent conditions." Applicant's arguments have been fully considered but they are not persuasive. The specification at page 23, lines 25-27, discloses one set of hybridization conditions, and, as noted in the last Office action, stringency varies according to the hybridization conditions and the particular hybrid under study. It is unclear what conditions are intended. If Applicants intend the term "stringent hybridization conditions" to only encompass those conditions set forth at page 23, lines 25-27, of the present specification, then Applicants should not hesitate in amending the claims to recite those conditions. Regarding the six U. S. Patents cited by Applicants, suffice it to say that each case must be decided on its own merits based on the evidence of record.

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Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's arguments have been fully considered but they are not persuasive.

Claim 42 is indefinite over the recitation of "bone morphogenetic protein-2." The recitation of  
5 "bone morphogenetic protein-2" is indefinite for the same reasons that the recitation of "BMP-2" is indefinite. Specifically, because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "bone morphogenetic protein-2" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set  
10 forth. It is suggested that the claim recite "bone morphogenetic protein."

Claims 24, 33, 35, 36, 38, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the  
15 relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that allelic variants are clearly defined in the specification at page 7, lines 4-18; that the specification at page 8, lines 10-16, describes sequences that differ due to the degeneracy of the genetic code or allelic variations; that Applicants have enabled the skilled  
20 artisan to identify and isolate nucleotides encoding BMP-2 from natural sources, which would provide the claimed allelic variants; that the term "allelic variant" is well understood in the art and Applicants cite 5 U. S. Patents, which claim allelic variants. Applicants' citation of U. S.

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Patent No. 5,586,388 (Method For Producing Multi-Board Electronic Device) appears to be an error.

Applicant's arguments have been fully considered but they are not persuasive. The specification at page 7, lines 4-18, and at page 8, lines 10-16, only provides a vague, general description of potential allelic variation. Furthermore, the specification at page 7, lines 4-18, and at page 8, lines 10-16, indicates that allelic variation may give rise to amino acid variation. Thus, allelic variants, as contemplated by the present specification, are not limited to degenerate variants. Even if the term "allelic variants" was construed as only encompassing degenerate variants, the present disclosure would not satisfy the written description requirement of 35 U.S.C. 112, first paragraph, because there is no specific description of the allelic variation that exist in nature, and there is no description of how the sequences in Figure 2 relate to the specific structure of any allele. The specification discloses only one allele within the scope of the genus: the nucleotide and amino acid sequence of figure 2. However, the general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. Therefore, applicants were not in possession of the claimed genus

**New Formal Matters, Objections, and/or Rejections:**

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***Priority***

Under 35 U.S.C. 120, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the

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manner provided by 35 U.S.C. 112, first paragraph in the earlier filed application. A polynucleotide comprising nucleotides 1202-1543 of Figure 2 or comprising nucleotides encoding amino acids 283 through 396 of Figure 2 was first disclosed in the manner provided by 35 U.S.C. 112, first paragraph, in U. S. Application No. 07/721,847 (filed 06/14/1991).

5 Accordingly, the effective filing date of the present claims that are directed to or encompass these embodiments is 06/14/1991. Should Applicants disagree, it is incumbent upon Applicants to provide the serial no. and specific place in any earlier filed application that specifically supports these embodiments. Furthermore, since the effective filing date of these embodiments is on or after October 1, 1990, the present application must comply with the sequence rules.

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The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the claims fail to recite the appropriate sequence identifiers, i.e., "SEQ ID NO:", at each place where a sequence is discussed. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not  
15 been checked to the extent necessary to determine the presence of all possible minor errors.

Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are  
20 specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need

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not be separately presented in the "Sequence Listing." Applicant may bring the figure(s) into compliance by amending either the figure(s) or the "Brief Description of the Drawings" to recite the appropriate sequence identifier.

Correction is required.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 25, 29, 33, 35, 36, 38, 39, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Wozney (U).

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This rejection is based upon an effective filing date of 06/14/1991 for claims that are directed to or encompass a polynucleotide comprising nucleotides 1202-1543 of Figure 2 or comprising nucleotides encoding amino acids 283 through 396 of Figure 2.

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Wozney discloses an isolated nucleic acid molecule, a vector comprising the isolated nucleic acid molecule in operative association with an expression control sequence, a host cell transformed with the vector, and a method comprising culturing the host cell and recovering the encoded polypeptide (paragraph bridging pages 1530-1531). Wozney's isolated nucleic acid molecule comprises nucleotides 1202-1543 of Figure 2 and comprises nucleotides encoding amino acids 283 through 396 of Figure 2, as indicated below (Qy = Figure 2 sequences) (Db = Wozney's sequences):

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Query Match

100.0%; Score 342; DB 9; Length 1547;



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Best Local Similarity 100.0%; Pred. No. 2.9e-103;  
Matches 342; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

5 Qy 1 CAAGCCAAACACAAACAGCGGAAACGCCTTAAGTCCAGCTGTAAGAGACACCCCTTTGTAC 60  
Db 1170 CAAGCCAAACACAAACAGCGGAAACGCCTTAAGTCCAGCTGTAAGAGACACCCCTTTGTAC 1229

10 Qy 61 GTGGACTTCAGTGACGTGGGGTGAATGACTGGATTGTGGCTCCCCCGGGGTATCACGCC 120  
Db 1230 GTGGACTTCAGTGACGTGGGGTGAATGACTGGATTGTGGCTCCCCCGGGGTATCACGCC 1289

15 Qy 121 TTTTACTGCCACGAGAAATGCCCTTTTCCTCTGGCTGATCATCTGAACTCCACTAATCAT 180  
Db 1290 TTTTACTGCCACGAGAAATGCCCTTTTCCTCTGGCTGATCATCTGAACTCCACTAATCAT 1349

20 Qy 181 GCCATTGTTTCAGACGTTGGTCAACTCTGTTAACTCTAAGATTCCTAAGGCATGCTGTGTC 240  
Db 1350 GCCATTGTTTCAGACGTTGGTCAACTCTGTTAACTCTAAGATTCCTAAGGCATGCTGTGTC 1409

25 Qy 241 CCGACAGAACTCAGTGCTATCTCGATGCTGTACCTTGACGAGAATGAAAAGGTTGTATTA 300  
Db 1410 CCGACAGAACTCAGTGCTATCTCGATGCTGTACCTTGACGAGAATGAAAAGGTTGTATTA 1469

Qy 301 AAGAACTATCAGGACATGGTTGTGGAGGGTTGTGGGTGTCGC 342  
Db 1470 AAGAACTATCAGGACATGGTTGTGGAGGGTTGTGGGTGTCGC 1511

30 Query Match 100.0%; Score 634; DB 1; Length 396;  
Best Local Similarity 100.0%; Pred. No. 5.1e-58;  
Matches 114; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

35 Qy 1 QAKHKQRKRLKSSCKRHPLYVDFSDVGWNDWIVAPPGYHAFYCHGECPPFLADHLNSTNH 60  
Db 283 QAKHKQRKRLKSSCKRHPLYVDFSDVGWNDWIVAPPGYHAFYCHGECPPFLADHLNSTNH 342

Qy 61 AIVQTLVNSVNSKIPKACCVPTLSAISMLYLDENEKVVLKNYQDMVVEGCGCR 114  
Db 343 AIVQTLVNSVNSKIPKACCVPTLSAISMLYLDENEKVVLKNYQDMVVEGCGCR 396.

#### 40 *Claim Objections*

Claims 33, 36, 39, 42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A polynucleotide that hybridizes to a polynucleotide complementary to a polynucleotide of claim 24, as recited in claim 33, fails to further limit a polynucleotide of claim 24 because the hybridization language encompasses

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nucleotide insertions, substitutions, deletions, additions and combinations of each of the forgoing with respect to a polynucleotide of claim 24.

Claim 41 is objected to the extent that it is directed to a nonelected invention.

**Conclusion**

Claims 26 and 30 are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
NOVEMBER 18, 2004